

Appl. No. 10/620,339
Amendment dated: December 8, 2004
Reply to OA of: September 8, 2004

REMARKS

Applicants acknowledge with appreciation the indication that claim 12 contains allowable subject matter. Applicants have not rewritten this claim in independent form since it is believed that the amendments to the claims obviate all of the outstanding rejections and places the application in condition for allowance.

Applicants have amended the claims taking into consideration the outstanding Official Action. Claim 1 has been corrected to make it complete as noted by the Examiner in the Official Action and the subject matter deleted from claim 2. Claims 5-10 have also been amended to conform the claim language compliant with 35 USC 112. Claims 13-17 have been similarly amended. Applicants most respectfully submit that all of the claims are in full compliance with 35 USC 112 and are clearly patentable over the reference of record.

The rejection of claims 1-9 and 13-19 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter with applicant regards as the invention has been carefully considered but is most respectfully traversed in view of the amendments to the claims which are fully supported by the application as originally filed and as would be appreciated by one of ordinary skill in the art to which the invention pertains. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 10, 11, 13, 15 and 16 are rejected under 35 USC § 102(b) as being anticipated by Zilla et al. (US2002/0151968 A1) has been carefully considered but is most respectfully traversed in view of the amendments to the claims.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical

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invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

Amended claim 10 is drawn to a multi-layer porous carriers comprising a hollow cavity surrounded by a wall of porous substrate and a porous structure located under the hollow cavity for cell attachment. Claim 11 further recites that tissue blocks of 500 to 1000 microns are contained. Amended claim 13 recites that the porous carrier is made of a bioabsorbable polymer material. Amended claim 15 recites that the multi-layer porous carrier is made of a composite material including a bioabsorbable polymer material. Amended claim 16 recites that said composite material includes collagen and poly(ethylene glycol) ("PEG"). These are all claim limitations which cannot be ignored.

Applicants most respectfully submit that Zilla teaches a multilayer ingrowth matrix, and its Figure 6 shows an inner cavity labeled 28, which is formed by a layer of PEG, as set forth in paragraph [0022] of the reference. Paragraph [0023] also teaches that other layers can be formed of collagen. However, the multilayer ingrowth matrix disclosed in the Zilla consists of either proteinaceous or synthetic layers or gradients. Each layer within the matrix is designed to achieve a specific function, such as facilitating ingrowth of a particular cell type or release of a particular growth factor (Abstract, line 2-7).

Additionally, Figure 2 shows a vascular graft 26 constructed from prosthetic material having a transmural scaffold with an ingrowth matrix 27 located within a network of spherical pores 36. The ingrowth matrix 27 in the prosthetic material of Zilla, as shown in Figure 3, preferably has at least three layers 28, 30 and 32 (paragraph [0022], line 1-6). The layers 28, 30 and 32 can be constructed from either proteinaceous or synthetic materials, or a combination wherein at least one layer is constructed from a proteinaceous material and at least one layer is constructed from a synthetic material (paragraph [0023], line 1-4). The protein layer refers a fibrin layer derivitized with

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peptides and/or growth factors is desirable...(paragraph [0024], line 1-2). A preferable synthetic layer is one constructed of PEG. PEG is an ideal polymer to engineer because unmodified it does not mediate cellular adhesion. It can, therefore, be specifically modified to mediate adhesion of only specific cell. (paragraph [0025], line 1-5).

As to the presently claimed invention, the Examiner's attention is most respectfully directed to page 6, line 1-4 of Applicants' specification and claim 10. Figure 1 shows a multi-layer porous carrier 1 which comprises an upper hollow cavity 2 for receiving tissue blocks, which is surrounded by a wall of porous substrate 3; and a porous structure 4, located under the hollow cavity 2, which is provided for cell attachment. Comparing with Zilla, the multi-layers disclosed in the present invention refer to an upper hollow cavity 2 surrounded by a wall of porous substrate 3 and a porous structure 4 located under the hollow cavity 2. However, the structure of the multi-layers disclosed in Zilla are the ingrowth matrix located within a network of spherical pores of the vascular graft. Accordingly, the structures disclosed in the present invention and Zilla are different from each other.

Additionally, Zilla teaches to utilize a prosthetic material having a transmular scaffold with an ingrowth matrix that comprises several layers, and each layer is designed to perform a specific function such as facilitation of ingrowth of a particular cell type or release of a particular growth factor. However, a multi-layer porous carrier disclosed in the present invention utilizes a novel structure design of porous carrier that can provide a proper environment for culturing tissues in vitro, finally these tissues can be used as implants in transplantation surgery. By using the porous carrier in the present invention, tissue blocks and cells are separated into different layers according to their sizes, and incubated in vitro to reconstruct a multi-layer tissue for tissue repair (Abstract, page 6). Apparently, the functions and mechanisms in Zilla and this invention are different.

Moreover, Zilla teaches that the material of the multi-layers in the matrix can be constructed from a proteinaceous material or synthetic materials, or a combination, wherein the preferable synthetic material is PEG because PEG can be specifically

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modified to mediate adhesion of only specific cell. See the page 4, line 13-27 of the specification, however, the multi-layer porous carrier in the present invention can be made of a bioabsorbable polymer material, such as PGA, PLA, PLGA, PCL, polydioxanone and polyorthoester or made of a composite material that comprising the foregoing absorbable polymer material and other materials, for example, HAP, TCP, TTCP, DCPA, DCPD, OCP, CPP..., collagen...and PEG. The material used to construct the carrier in this invention does not need to be modified to mediate adhesion of only specific cell.

Hence, Zilla cannot anticipate claim 10 of the present invention. The claim 10 is patentably distinguished over Zilla. Insofar as claims 11, 13, 15 and 16 depend upon claim 1 directly or indirectly, therefore these claims are also patentably distinguished over Zilla.

For the reason discussed above, reconsideration and withdrawal of the examiner's rejection under 35 USC §102 (b) is respectfully requested.

In light of the above amendments to the claims and remarks, applicant respectfully submits that the pending claims 1-19 as currently presented are in condition for allowance and respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
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